UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

JUDY WETHINGTON, et al.,	:	NO. 1:01-CV-00441
Plaintiffs,	:	
	:	**ORDER**
v.	:	
PURDUE PHARMA LP, et al.,	:	
Defendants.	:	

This matter is before the Court on Plaintiffs' Amended Motion for Class Certification (doc. 54), Abbott Laboratories' Response in Opposition (doc. 66), Purdue Defendants' Response in Opposition (doc. 68), Plaintiffs' Reply (filed under seal)(doc. 74), Abbott's SurReply (doc. 87), and Purdue's SurReply (doc. 88). The Court held a hearing on this matter on August 12, 2003.

I. Background

This case concerns the pharmaceutical drug OxyContin, a federally controlled Schedule II opioid prescription medication, approved by the Food and Drug Administration in December 1995 for use in the management of moderate to severe pain. OxyContin, sold in tablet form, is designed to provide time-released delivery of its active ingredient oxycodone hydrochloride. Like many prescription pharmaceuticals, the drug can be abused. When the tablet is crushed, the time-release mechanism is destroyed and the

person ingesting the drug can obtain a feeling of euphoria similar to that experienced when taking heroin.

In 2002 OxyContin was the number one prescribed Schedule II narcotic in the United States, accounting for 9.6 million prescriptions. The United States Drug Enforcement Agency ("DEA") lists the contiguous states of Ohio, Kentucky, and West Virginia as having the highest prescriptions of the drug per capita.

Defendants Purdue Pharma L.P., Purdue Pharma, Inc., the Purdue Frederick Company, Purdue Pharmaceuticals L.P., the P.F. Laboratories, Inc., and PRA Holdings, Inc. (collectively, hereinafter, "Purdue") manufacture the drug, while Defendants Abbott Laboratories and Abbott Laboratories, Inc. (hereinafter, "Abbott") have provided promotional assistance in its marketing. Plaintiffs allege, under ten differing legal theories [1], that Defendants' actions have resulted in risks of serious bodily harm, addiction, and death to members of their proposed class (doc. 57). Plaintiffs presently seek certification of the following class under Fed. R. Civ. P. 23:

> All Ohio, Kentucky, Indiana, and West Virginia residents who first used OxyContin after receiving a legal

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[1]Plaintiffs' Second Amended Complaint includes causes of action for (1) strict product liability, (2) negligence, (3) failure to warn, (4) breach of express warranty, (5) breach of implied warranty, (6) violation of state consumer sales practices acts, (7) fraud, (8) conspiracy, (9) unjust enrichment, and (10) injunctive and equitable relief, (doc. 57).

> prescription between the years 1995 and the date of class certification. The class also includes those individuals who have loss of consortium claims.

On April 24, 2003, the Court delayed consideration of Plaintiffs' Motion for Class Certification, pending a motion to consolidate federal "OxyContin related" litigation before the Judicial Panel on MultiDistrict Litigation ("JPML")(doc. 77). Shortly thereafter, on June 17, 2003, the Judicial Panel on Multidistrict Litigation granted a motion to withdraw a motion for centralization of twenty related actions to the District of South Carolina. See In Re OxyContin Products Liability Litigation, 268 F. Supp. 2d 1380 (2003)(doc. 99). In light of this development, on June 25, 2003, the Court scheduled the August 12, 2003 hearing on class certification.

The question of class certification of an OxyContin-related class has been handled recently by two different courts that arrived at different conclusions. The Court finds reference to such opinions particularly relevant because they were written by courts in Kentucky and Ohio, two of the jurisdictions encompassed by Plaintiffs' putative class definition.

On February 25, 2002, the Honorable Judge Danny C. Reeves denied a motion to certify a class of "all persons who have been harmed due to the addictive nature of OxyContin," in Foister v. Purdue, No. 01-268-DCR, 2002 U.S. Dist. LEXIS 8192 (E.D. Ky.,

February 26, 2002).[2] Although the Foister Court considered Plaintiffs' argument that it could limit the class to those persons who received OxyContin through written prescriptions, the court nonetheless rejected such class definition as vague and calling for subjective, individualized medical conclusions. Id. at *17-*18. Judge Reeves further concluded that a number of Fed. R. Civ. P. 23 requirements were not met. Id. at *5-*11. Specifically, the Court found the plaintiffs failed to demonstrate (1) that joinder was impracticable; (2) that common questions of law and fact exist; (3) the typicality of the class representatives' claims; and (4) that the plaintiffs could fairly and adequately protect the interests of the putative class. Id.

Judge Reeves reached a similar conclusion in a subsequent case, Gevedon v. Purdue Pharma, 212 F.R.D. 333 (E.D. Ky. 2002). Plaintiffs purported to define the class as "[a]ll persons in the Commonwealth of Kentucky who have obtained OxyContin and/or who

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[2] Of particular interest to this Court is Judge Reeves' observation that plaintiffs' counsel in Foister sought to withdraw their motion before his court and to obtain certification over its putative class in this Court, "for fear" that the Eastern District of Kentucky "would not address their class certification motion issue in a timely way." Foister, 2002 U.S. Dist. LEXIS 8192 at *3. Defendants objected to Plaintiffs' attempt to withdraw their motion, arguing that Plaintiffs' actions constituted improper forum shopping. Id. at *4. Judge Reeves declined to accept Plaintiffs' attempt to withdraw the pending motion and thus addressed the issue of class certification. Id. at *3-*4.

obtain OxyContin in the future." Gevedon, 212 F.R.D. at 336. The court found this definition lacking:

> The Plaintiffs seek to certify a class based on medical problems, addiction, and damages resulting to those who "obtain" OxyContin® and suffer addiction and other adverse conditions. In order [to] determine the Defendant's liability under these allegations, the Court or jury would be faced with a number of questions that are highly individualized in nature and call for plaintiff-specific information. Such an inquiry would include where the putative class member obtained the drug, whether possession of the drug was legal, and whether each member was, in fact, injured as a result of obtaining the drug. Further inquiries would include the assurances each Plaintiff received from his treating physician, individual medical histories, dosage and length of prescriptions and method of taking the drug. Basically, this Court would need to determine, consider and resolve a number of highly subjective facts, many of which are dependent on the state of mind of particular individuals, in order to ascertain whether any given individual is within or outside the alleged class.
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> As a result, the Court concludes that this definition is vague and calls for subjective medical conclusions. The present case is unsuitable for certification because each putative class member's state of mind requires litigating each individual case. Even limiting the class to those individuals who legally obtained the drug does not remedy the large number of individual issues that still remain. The proposed class is so highly diverse and so difficult to ascertain that it is not adequately defined. Thus, this Court concludes that an initial, inherent element of class certification fails for lack of a definable, identifiable class.

Id. at 336-37. Judge Reeves further concluded that the plaintiffs also failed to satisfy the numerosity, typicality, and adequacy requirements of Fed. R. Civ. P. 23. Id. at 337-342. This case was

terminated with prejudice by agreement of the parties on November 20, 2002.

By contrast, the Court of Appeals of Ohio, Twelfth Appellate District, affirmed certification under Ohio Civil Rule 23 of a class of plaintiffs who "suffered" after securing OxyContin through a lawful prescription. Howland v. Purdue Pharma, L.P., Nos. CA2002-09-220, CA2002-09-223, CA2002-09-227, 2003 Ohio App. LEXIS 3347 (Ohio Ct. App., July 14, 2003).[3] The Ohio court found that the trial court had not abused its discretion in certifying the class. Id. at *9. In its analysis, the court found the evidence of over one million prescriptions filled in Ohio to establish numerosity. Id. at *11. The court further found the proposed representatives adequate to represent members of the proposed class and to possess claims typical of the class. Id. at *12-*13. In addition, the court found persuasive Plaintiffs' evidence that Defendants "engaged in a common, class-wide course of conduct" in allegedly failing to issue warnings about OxyContin's addictive nature, the danger of crushing the tablet, and the inappropriateness of its use for certain ailments like arthritis pain. Id. at *16. The court also found common issues in

[3] Defendants appealed such decision, which is currently pending before the Ohio Supreme Court. See Purdue Pharma, et al., Appellants v. Howland, et al., Appellees, No. 03-1538, filed August 28, 2003.

Plaintiff's allegations that Defendants' promotion of the drug was false and misleading, and that Defendants defectively designed the drug to lack an antagonist that would eliminate its harmful effects if crushed. Id. The court concluded that the trial court did not abuse its discretion in determining that the common questions predominated over individual questions, and therefore a class action is the superior method of resolving this controversy. Id.

II. Threshold Issues

Before even reaching the question of class certification, Defendants have raised a number of issues that the Court finds appropriate to address. As explained herein, the Court does not find these issues to preclude it from conducting a Fed. R. Civ. P. 23 analysis.

A. Collateral Estoppel

In light of the fact that state-wide certification has already been denied twice in Kentucky, Defendants argue that the attempt to add Kentucky to the proposed class here is a back-door attempt to avoid appealing the denials in Kentucky, while forum shopping for a more sympathetic court.[4] Defendants' argument implicitly requests the Court to defer to the determination of the

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[4] Defendants also argue that the Southern District of West Virginia is also considering for certification a state-wide class for West Virginia residents who "purchased and ingested OxyContin," and thereafter suffered damages. However, shortly after Defendants submitted such argument, that court issued a decision denying class certification based on the plaintiffs' motion to dismiss the litigation. Baker v. Purdue Pharma, L.P., No. 1:01-0553, 2003 U.S. Dist. LEXIS 6632 (S.D. W.V. March 31, 2003).

Eastern District of Kentucky, under the theory that the Court is collaterally estopped from reaching the same question.

Counsel for the Defendants argued at the August 12, 2003 hearing that collateral estoppel would apply to this matter. However, at this juncture, this is not the case for a number of reasons. First, and most fundamentally, collateral estoppel only bars the Court from considering an issue when that issue was litigated, determined, and necessary to the judgment in a prior case involving the same parties. Restatement (Second) of Judgments §§ 27 ("When an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim"). As there has been no final judgment in the Eastern District of Kentucky, collateral estoppel does not apply to the putative class members hailing from the Commonwealth of Kentucky. Second, if there was a final judgment in the Eastern District of Kentucky, such judgment would not apply to putative class members in West Virginia, Ohio, or Indiana, as those class members were not parties to that litigation. Martin v. Wilks, 490 U.S. 755, 762 (1989)("A judgment or decree among parties to a lawsuit resolves issues as among them, but it does not conclude the

rights of strangers to those proceedings"). In that event, the Court could simply tailor the class to exclude class members from the Commonwealth of Kentucky.

Plaintiffs signal that Defendants failed to mention the class certification upheld by the Ohio Court of Appeals, arguing that if the Court should grant deference to the Eastern District of Kentucky, it should likewise grant deference to the Ohio decision, Howland, 2003 Ohio App. LEXIS 3347 (Ohio Ct. App., July 14, 2003). However, the Court is not collaterally estopped by the Ohio decision either. The Howland certification was not made pursuant to Fed. R. Civ. P. 23. Howland is currently subject to appeal and is therefore not yet final. Finally, Howland certified a class definition that, though arguably extremely similar, is not identical to that proposed class definition presently before the Court.

Having rejected the argument that the Court is collaterally estopped by the class certification decisions of either its sister court in the Eastern District of Kentucky or the Ohio Court of Appeals, the Court nonetheless has considered the reasoning of such decisions and shall accord them persuasive authority as it deems appropriate.

B. Problems with the Class Representatives

Defendants present facts about three proposed class representatives, David Wethington, Rita Smith, and Karen Eicher, in order to show their unique medical circumstances and inherent individuality, thus showing the inappropriateness of class

certification (doc. 68). Defendants further argue that Wethington's claims are time-barred by the Ohio two-year statute of limitations for personal-injury wrongful-death actions (Id.).

The Court finds that just as it is axiomatic that a trust shall not fail for want of a trustee, Kenan v. Bowers, 50 F. 2d 112 (2d Cir. 1931), similarly a class should not fail due to problems with some of the proposed class representatives. Although, for example, Wethington's claims may indeed be time-barred, such fact does not preclude the potential existence of class members whose claims are not. Similarly, the unique problems of some representatives do not preclude the potential existence of other representatives who might adequately represent the class. The Court finds well-taken Plaintiffs' position that the existence of individual issues does not necessarily preclude a class action on the question of liability, in the event that such a common question exists, the resolution of which will advance the litigation. Sterling v. Velsicol Chemical Corp., 855 F.2d 1188, 1197 (6th Cir. 1988)("the mere fact that questions peculiar to each individual member of the class remain after the common questions of the defendant's liability have been resolved does not dictate the conclusion that a class action is impermissible"), Sprague v. General Motors Corp., 133 F.3d 388, 397 (6th Cir. 1998)(en banc). As a threshold issue, therefore, the Court will not refrain from Fed. R. Civ. P. 23 analysis based on arguments that there are problems with the class representatives.

C. Defendants' Argument that Class Members Lack Standing

Defendants next argue that some class members lack standing because they lack injury-in-fact under Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992). Defendants argue that Plaintiffs' proposed class thus wrongly includes people who have taken the drug without ill effects and who are satisfied with it, people who took it briefly years ago and stopped taking it without incident, and people who received OxyContin as a palliative treatment while on their deathbed.

The Court finds Defendants' arguments on this point persuasive. However, such problem could be addressed with a modification of the class definition to include "harm" or "suffering" like the respective definitions in Foister, 2002 U.S. Dist. LEXIS 8192 (E.D. Ky., February 26, 2002), and Howland, 2003 Ohio App. LEXIS 3347 (Ohio Ct. App., July 14, 2003). Such problem does not preclude the Court from conducting Fed. R. Civ. P. 23 analysis.

D. Defendants' Argument That Class Certification is Inappropriate in a Pharmaceutical Personal-Injury Products-Liability Action Such as This

Defendants argue that unlike a mass tort action arising out of a single accident or single course of conduct, in a medical products liability action, the factual and legal issues often differ dramatically from individual to individual (doc. 68). They argue that this proposition has been established in the Sixth Circuit under American Medical Systems, 75 F. 3d 1069, 1090 (1996), and has been followed by courts across the country in denying class certification in single product products liability personal-injury

lawsuits (Id.). At least four decisions have been handed down in the last year alone denying class certification in such cases: In re Paxil Litig., Case No. CV 01-07937 MRP, 2003 U.S. Dist. LEXIS 1936 (C.D. Cal. Jan. 10, 2003)(denying motion to certify class of users of a prescription antidepressant and anti-anxiety medication); In re Rezulin Prod. Liability Litig., 210 F.R.D. 61 (S.D.N.Y. 2002)(denying motion to certify class of users of a prescription diabetes medication), In re Phenylpropanolamine (PPA) Prod. Liability Litig., 208 F.R.D. 625 (W.D. Wash. 2002); In re Propulsid Prods. Liability Litig., 208 F.R.D. 133 (E.D. La. 2002)(denying motion to certify class of users of a prescription heartburn medication)(Id.).

The Court does not find well-taken the proposition that pharmaceutical personal-injury products-liability actions are, as a rule, inappropriate for class certification. See e.g., In re Diet Drugs Products Liability Litigation, No. 98-20606, 1999 U.S. Dist. LEXIS 13228 (E.D. Pa. Aug. 26, 1999); Valentino v. Carter-Wallace, 97 F.3d 1227 (9th Cir. 1996)(although the Ninth Circuit vacated and remanded class certification, it rejected the proposition that there is "any absolute bar to the certification of a multi-state class action in the medical products liability context"). Such actions by their nature may tend to be characterized by individual issues, yet if individual issues are outweighed by common issues, class certification may be appropriate under Fed. R. Civ. P. 23. Sterling v. Velsicol Chemical Corp., 855 F.2d 1188, 1197 (6th Cir. 1988).

III. Class Certification Under Fed. R. Civ. P. 23

There are four prerequisites to a class action, found in Fed. R. Civ. P. 23(a):

> One or more members of a class may sue or be sued as representative parties on behalf of all only if : (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

Although Rule 23(a)(2) refers to common questions of law or fact, in the plural, there need only be one question common to the class-though that question must be a "common issue the resolution of which will advance the litigation." Alkire v. Irving, 330 F.3d 802, 820 (6th Cir. 2003) (citing Sprague v. Gen. Motors Corp., 133 F.3d 388 (6th Cir. 1998)(en banc), and Amchem Prods, Inc. v. Windsor, 521 U.S. 591, 623 (1997). Ultimately, the class may only be certified if, "after rigorous analysis," the

district court is satisfied that these prerequisites have been met. Gen. Tel. Co. v. Falcon, 457 U.S. 147, 161 (1982). The burden is on the plaintiff "to establish his right" for class certification. Senter v. General Motors Corp., 532 F.2d 511, 522 (6th Cir. 1976).

If the Plaintiffs can establish the four prerequisites for class certification found in Rule 23(a), numerosity, commonality, typicality, and representativeness, then they must show that, in addition, they satisfy one of the three types of class actions found in Fed. R. Civ. P. 23(b). A type I class action under 23(b) is appropriate when separate actions would create incompatible standards of conduct for the party opposing the class, or when the interests of members not parties to the litigation would be impeded by individual adjudications. Fed. R. Civ. P. 23(b)(1). A type II class action requires that the plaintiff seek primarily injunctive or declaratory relief. Fed. R. Civ. P. 23(b)(2). A type III class action requires that common questions of law or fact predominate over any issues affecting only individual members and therefore a class action is superior to other available methods for the fair and efficient adjudication of the controversy. Fed. R. Civ. P. 23(b)(3).

Plaintiffs in this case argue that their proposed class meets the four prerequisites of Rule 23(a) and that their class can be certified as type I, II, or II under Rule 23(b).

A. Rule 23(a)(1): Numerosity

The first requirement of Rule 23(a) is that the class be

so numerous that joinder of all members would be impracticable. Fed. R. Civ. P. 23(a)(1). The plaintiff need not demonstrate that it would be impossible to join all the class members; rather, he need simply show that joinder in this case would be difficult and inconvenient. Day v. NLO, Inc., 144 F.R.D. 330, 333(S.D. Ohio 1991); see also Boggs v. Divested Atomic Corp., 141 F.R.D. 58, 63 (S.D. Ohio 1991) (stating "[s]atisfaction of the numerosity requirement does not require that joinder is impossible, but only that plaintiff will suffer a strong litigational hardship or inconvenience if joinder is required"). There is no strict numerical test used to determine whether joinder is impracticable. Senter, 532 F.2d at 523. Instead, the Court must examine the specific facts of each case. General Tel. Co. of Northwest, Inc. v. EEOC, 446 U.S. 318, 330 (1980). In determining numerosity, the Court "may consider reasonable inferences drawn from facts before him at the stage of the proceedings." Senter, 532 F.2d at 523. This court, in Basile v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 105 F.R.D. 506 (S.D. Ohio 1985) found that as few as twenty-three class members could satisfy the requisite numerosity. Id. at 508 ("Paraphrasing another district court's view of the first requirement of the rule, while 23 may not be a large number when

compared to other classes that have been certified, it is a large number when compared to a single unit; there is no reason to encumber the judicial system with 23 consolidated lawsuits when one will do.")(citing Philadelphia Electric Co. v. Anaconda American Brass Co., 43 F.R.D. 452 (E.D.Pa. 1968)).

Plaintiffs contend that based on the estimated sales of the drug in Kentucky, Ohio, Indiana, and West Virginia their proposed class meets the numerosity requirement (doc. 54). Defendants argue that Plaintiffs have not produced any evidence of or even an estimate of the number of potential putative class members. They argue that the Eastern District of Kentucky rejected attempts to establish numerosity based on sales figures of OxyContin alone, finding that the mere purchase of a product alone does not put an individual into the purported class. Gevedon v. Purdue Pharma, 212 F.R.D. 333, 338 (E.D. Ky. 2002). Defendants argue that the privacy laws in the four states preclude Plaintiffs from establishing numerosity through prescription records. Due to such privacy laws, Defendants argue there is no way to determine if three prescriptions belong to one, two, or three different people, whether the prescription was "legal," whether the "first legal" prescription predated the initial ingestion of OxyContin, or whether its recipient suffered any injury. Plaintiffs responded at the August 12, 2003 hearing that the privacy laws have in no way barred them in past drug litigation, as they could hire an independent company to procure prescription information from doctors and pharmacists, thereby notifying class members

independently under the auspices of the Court in a confidential manner. Plaintiffs further suggested that publication in major national newspapers could ensure that all class members would receive notice.

The Court finds that taking reasonable inferences in favor of Plaintiffs, and accepting as true their representation that they can respect the privacy laws at issue while concurrently establishing numerosity through prescription records, Plaintiffs have met the numerosity requirement of Rule 23(a)(1). Plaintiffs represent that in Ohio alone there were almost a million prescriptions in one year. Although one million prescriptions does not necessarily translate into one million claimants, Plaintiffs have further submitted three hundred adverse event reports submitted to the FDA, documenting alleged problems with withdrawal and dependency. For purposes of its numerosity analysis, the Court finds credible the proposition that an adequate number of people are allegedly adversely affected by OxyContin to render joinder impracticable.

B. Rule 23 (a)(2): Commonality

In order to satisfy Rule 23(a)(2), there must be "questions of law or fact common to the class." Fed. R. Civ. P.

23(a)(2). The commonality requirement is satisfied "as long as the members of the class have allegedly been affected by a general policy of the defendant and the general policy is the focus of the litigation." Day, 144 F.R.D. at 333 (quoting Sweet v. General Tire & Rubber Co., 74 F.R.D. 333, 335 (N.D. Ohio 1976))(emphasis in original). The commonality test is qualitative, not quantitative. 1 Herbert B. Newberg and Alba Conte, Newberg on Class Actions, § 3.10 at 3-50 (3d ed. 1992). There need be only a single question of law or fact common to all members of the class. Id. "[T] he mere fact that questions peculiar to each individual member of the class remain after the common questions of the defendant's liability have been resolved does not dictate the conclusion that a class action is impermissible." Sterling v. Velsicol Chemical Corp., 855 F.2d 1188, 1197 (6th Cir. 1988). However, the existence of any common question is insufficient because "at a sufficiently abstract level of generalization, almost any set of claims can be said to display commonality." Sprague, 133 F.3d 388, 397 (6th Cir. 1998)(en banc). As noted above, "[w]hat [the court looks] for is a common issue the resolution of which will advance the litigation." Id.

Plaintiffs argue that there are a number of questions of law and fact common to the individuals comprising the class (doc. 54). They argue that the drug was marketed and promoted in a misleading manner, and that Defendants knew or should have known of

the harmful effects of such promotion and marketing (Id.). They argue that the Purdue Defendants are liable for manufacturing a defective, highly addictive product that lacks an antagonist agent to prevent its euphoric effects when crushed and ingested (Id.). Plaintiffs further allege Defendants are liable for failure to properly warn consumers, and for continuing to promote and market the drug notwithstanding their knowledge of its harmful side effects (Id.). Plaintiffs allege that Defendants knowingly concealed facts about the harmful nature of the drug from the medical community and/or the public (Id.). They state that there exists beneficial monitoring and testing procedures for which certain class members share the right to reimbursement (Id.). They argue that all class members received nearly identical information about the drug, and all suffer from the same defect (Id.). Finally, Plaintiffs argue that Defendants are liable for punitive damages--a common legal determination applicable to the claims of the putative class (Id.).

Purdue argues that Plaintiffs fail to demonstrate that common issues exist, because all of their professed common issues focus on Defendants' conduct rather than on the individualized medical histories of the putative class members (doc. 68). Defendants argue that marketing and promotional activities are not "common" because they are relevant only if individualized exposure, reliance, and proximate cause can be shown (Id.). Defendants argue that because they do not engage in direct-to-consumer advertising, but rather marketing to doctors, Plaintiffs will need to show that

each doctor was exposed to misleading marketing and was misled, thus resulting in a decision to prescribe the drug (Id.). Defendants further argue that the OxyContin package insert highlights the individuality in patient treatment, and the effect of its warnings cannot be evaluated absent a determination of what the patient already knew about the drug (Id.). Defendants argue that the package insert clearly indicates the potency of the drug, so that Plaintiffs' allegation that Defendants misled the medical community has no basis in fact and is therefore not a common issue (Id.). Finally, Defendants argue that Plaintiffs' theory that the drug is defective for lack of an antagonist is relevant only to those class members who misused the product by crushing it (Id.). Moreover, Defendants argue, the claims of those people who intentionally crushed the drug would likely be barred by Ohio, West Virginia, or Indiana law as intentional product misuse (Id.).

The Abbott Defendants largely echo the arguments of Purdue, while emphasizing Abbott's limited role in marketing the drug to physicians (doc. 66). As such, Abbott never manufactured, distributed or sold the drug (Id.). Abbott argues that Plaintiffs have not alleged any nexus between any of them nor identified any conduct that caused them to take the drug or to cause alleged injuries (Id.).

Abbott argues that it did not engage in any class-wide course of conduct that affected all potential class members, and that Plaintiffs' alleged common conduct involves activities in which Abbott did not participate (Id.). Abbott argues that the

only claims even arguably available against them are a series of discrete negligence claims based on Abbott's promotion of the drug to particular doctors who prescribed the drug to individual Plaintiffs (Id.). Like Purdue, Abbott argues that such negligence claims would require proof of proximate causation, an inquiry requiring analysis of individual causation that is incompatible with class treatment (Id.).

In their Reply (doc. 74), Plaintiffs re-frame four common issues, the resolution of which they posit would materially advance this litigation:

> 1) whether OxyContin is defective because it was not distributed in lower dosages safer for opioid-naive patients, for lack of an antagonist, for failure to warn the medical community and/or patients of the drug's risks, and for being more dangerous than an ordinary consumer would expect.
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> 2) whether Purdue and Abbott conspired to sell, distribute, market, and produce a defective drug.
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> 3) whether Abbott generally participated in the sale of the drug.
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> 4) whether OxyContin creates addiction and physical dependence.

Defendants requested and were granted leave to file SurReply (doc. 88), because Plaintiffs' Reply introduced a new issue concerning the level of dosages marketed to "opioid-naive" patients, that is, according to Plaintiffs' definition, patients who had not received an opioid medication for the pain associated with their current complaint. Purdue Defendants argue that missing from Plaintiffs' arguments is testimony before Congress on behalf of the FDA that the benefits of the drug outweighed its risk when

used according to labeling, and that the FDA believes the drug is a valuable product for the treatment of moderate to severe pain when used according to the approved labeling (doc. 88). Also missing--citation to the medical records of the proposed class representatives that shows that they were not opioid naive when first prescribed OxyContin, but that they had been prescribed other opioid drugs in the past (Id.).

Purdue Defendants argue that Plaintiffs' new argument that the drug should have been marketed in smaller dosages is based on a non-physician's opinion, while the dosage marketed went through extensive FDA required testing and an application prior to approval (Id.). Further, all but one of Plaintiffs' representatives, argue Purdue, were prescribed a dosage greater than the smallest on the market at the time, 10 mg (Id.). It defies reason, therefore, argues Defendant, to claim that if physicians did not prescribe the 10mg tablet, why they would need to prescribe an even smaller dosage (Id.). The Court finds Defendants' argument well-taken.

Purdue Defendants argue that the Learned Intermediary Doctrine, which they apparently glean from Plaintiffs' "failure to warn the medical community" theory, is not a common issue because its resolution does not depend on common facts or circumstances of members of the class-but rather warnings given to doctors. Each patient then receives different information and assurances from his doctor.

Purdue argues that Plaintiff's arguments about an

"antagonist" do not constitute a common issue as there is nothing in the record to support the fact that an antagonist has been developed that will work with OxyContin. Purdue further argues that an antagonist cannot be a common issue to those class members who took OxyContin as directed by their doctor. The Court finds these arguments well-taken.

In reviewing the commonality prong of the Rule 23 analysis in Foister, 2002 U.S. Dist. LEXIS 8192, at *24-*26, Judge Reeves found that the same sorts of claims at issue in this case, for negligence, failure to warn, manufacturing defect, negligence per se, conspiracy, breach of warranty, fraud, and statutory claims "will vary from Plaintiff to Plaintiff." Id. at *25. Judge Reeves reasoned that "any harm suffered by Plaintiffs may be due to a number of factors, including, dosage, use and manner of administration of the drug, individual and family medical and psychological histories, level of personal awareness regarding the purported risk and medical reasons for use." Id. at *25-*26. As such, each Plaintiff would be required to testify to issues of reliance, causation, and damages. Id. at *26. Consequently, Judge Reeves found that each of the claims depended on questions of fact and law peculiar to each individual so that there was not sufficient commonality for a class to be certified. Id. at *26. Judge Reeves arrived to the same conclusion in Gevedon, adding, "[w]hile there may be some common questions regarding Defendants' alleged actions or inactions, because other elements for a class action are not met, the Court does not find it necessary to resolve

this issue at this time." 212 F.R.D. 333, 339 (E.D. Ky. 2002).

The Court finds the reasoning of Judge Reeves on point to the question of class certification in this case. Defendants' arguments that the harm allegedly suffered by each class member may be due to a number of individual factors is well-taken. The factual circumstances of addiction are individualized. Dhamer v. Bristol-Myers Squibb Co., 183 F.R.D. 520, 529 (N.D. Ill. 1998).

The Court notes, however, the appeal of the marketing argument. The Ohio Supreme Court recently found that the marketing of a legally regulated dangerous product, firearms, could provide the basis for a Complaint that should withstand a motion to dismiss. Cincinnati v. Beretta U.S.A. Corp. et al., 95 Ohio St. 3d 416 (Ohio 2002). Similarly, the Court finds that if Defendants in

this case were creating a public nuisance through intentional and negligent conduct, such conduct might constitute a common issue that could serve to meet the commonality prong of Rule 23.

However, the key distinction in this case precluding such a conclusion is that regardless of any alleged improper marketing, in order to obtain the product, a class member must make a request to a Learned Intermediary.[5] This is the case because the putative class definition encompasses those who have a "legal prescription" of OxyContin. If the Learned Intermediary, when adequately warned himself or herself, fails to understand the danger inherent to the product he or she is prescribing, prescribes too high of a dosage or too large a quantity for a particular patient, then that patient, if injured, may actually have a malpractice claim against the physician. See, e.g., Robert Lee Martin III v. Ortho Pharmaceutical Corp. 661 N.E. 2d 352, 353 (Ill. 1996).

In this case, Defendants proffer evidence showing that

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[5] The Learned Intermediary Doctrine has been adopted by the Ohio Supreme Court and has been applied in product liability actions involving prescription drugs. Seley v. G.D. Serle & Co., 67 Ohio St. 2d 192, 423 N.E. 2d 831 (1981); Tracy v. Merrell Dow Pharmaceuticals, Inc., 58 Ohio St. 3d 147, 569 N.E. 2d 875 (1991). The doctrine operates as an exception to the manufacturer's duty to warn the ultimate consumer and shields manufacturers from liability where the warning to the prescribing physician is adequate. "The rationale behind these holdings is that the physician stands between the manufacturer and the patient as a learned intermediary. The physician has the duty to know the patient's condition as well as the qualities and characteristics of the drugs or products to be prescribed for the patient's use." Tracy, 569 N.E. 2d at 878. In other words the duty to warn is discharged to the physician on the basis of the adequate warnings provided to that physician by the manufacturer.

there have always been disclosures in the package insert that set forth the relative potency of OxyContin as compared to morphine and other opioids (doc. 68). Defendants signal that Purdue has provided a table in the package insert instructing physicians as to the relative potency of the drug (Id.). Specifically, such table instructs that when converting the daily dose of prior opioids, including morphine, to the daily dose of oral oxycodone, the appropriate dose of oral oxycodone is equal to half the current dose of morphine (Id.). As such, Defendants state that they have always told doctors that oxycodone, and therefore OxyContin, is twice as potent as morphine, a potentially addictive drug (Id.). The Court finds that doctors were adequately warned of the powerful dosage of OxyContin relative to morphine, and thus the Learned Intermediary Doctrine discharges the duty to warn from the manufacturer to the physician.

Liability, in this case, therefore, turns on individual determinations. The Court finds therefore that Plaintiffs' proposed common issues are either individualized in nature, or, when premised upon Defendants' conduct, are trumped by the existence of individual Learned Intermediaries. In re Baycol Products Litigation, MDL No. 1431, 2003 U.S. Dist. LEXIS 16341,

*17-18 (D. Minn. September 17, 2003)(denying class certification of those who ingested the prescription drug Baycol, noting that the claims involved individual issues such as injury, causation, the Learned Intermediary Doctrine, and comparative fault).

Having found that Plaintiffs failed to meet the commonality prong of Rule 23(a)(2), the Court need not reach the remainder of the prerequisite analysis of typicality or adequate representativeness. For the same reason, the Court need not engage in any Rule 23(b)analysis.

IV. CONCLUSION

The Court finds that Plaintiffs in this case have not come forward with a common issue, the resolution of which will advance this litigation. Plaintiffs' claims are inherently individualized, requiring an inquiry into questions of fact and law peculiar to each class member. Plaintiffs' claims based on Defendants' actions in manufacturing and/or marketing OxyContin cannot constitute a common issue because of the existence of individual learned intermediaries, physicians, who prescribed the drug to their patients.

There is no question that OxyContin, like many other powerful prescription drugs, can be dangerous when it is not used as directed, or when it makes it to the street. Testimony before Congress, on behalf of the FDA, however, indicates that the

benefits of the drug outweighed its risk when used according to the approved labeling, and that the FDA believes the drug is a valuable product for the treatment of moderate to severe pain when properly used. As defined in their Motion, Plaintiffs' proposed class includes people who have a valid prescription, and who may very well have a new lease on life.

In summary, the Court finds too many problems with Plaintiffs' proposed class definition, and there are too many individual factual issues dealing with strict liability, negligence, failure to warn, and the host of affirmative defenses raised by the Defendants.

Accordingly, Plaintiffs' Amended Motion for Class Certification (doc. 54) is DENIED.

SO ORDERED.

Dated: September 30, 2003

s/S. Arthur Spiegel
S. Arthur Spiegel
United States Senior District Judge